Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) 022719-0046

	Application Number	Filed
	10/642,772-Conf. #3663	August 18, 2003
	First Named Inventor: Meir Rosenberg	
	Art Unit: 3736	Examiner: J. G. Hoekstra

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 44,238
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. ____

/Lisa Adams/
Signature

Lisa Adams
Typed or printed name

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Telephone number

June 11, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of 1 forms are submitted.

Pre-Appeal Brief Request for Review

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: June 11, 2008 Electronic Signature for Lisa Adams: /Lisa Adams/

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Meir Rosenberg	
Application No.:	10/642,772	Group Art Unit: 3736
Filed:	August 18, 2003	Examiner: Jeffrey Gerben Hoekstra
Entitled:	TRIMMABLE SENSING CATHETER	
Docket No.:	22719-46 (COD-5013)	

Certificate of Transmission (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being electronically filed via **EFS-Web** to: **MS Amendment,** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date set forth below.

June 11, 2008	By: Electronic Signature: /Lisa Adams/
Date of Signature and Mail Deposit	Lisa Adams, Reg. No: 44,238 Attorney for Applicant(s)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS FOR PRE-APPEAL BRIEF REVIEW

Dear Sir:

These comments are being filed concurrently with a Notice of Appeal and a Pre-Appeal Brief Request for Review.

Claims 1-11, 13, 15-25, and 27 are pending and stand rejected.

Previous Panel Decision

At the outset, Applicant notes that in the July 19, 2007 Notice of Panel Decision from Pre-Appeal Brief Review, the panel agreed to withdraw the pending rejections and issue a new Office Action. However, in the Office Actions mailed on October 4, 2007 and March 13, 2008, the Examiner issued the same rejection that was withdrawn by the panel. In the Office Action dated March 13, 2008, the Examiner asserts that although the pending rejection relies on the same art, the Examiner presents a "different interpretation" of the previously applied references. Accordingly, while Applicant provides the following additional remarks in response to the pending rejections,

Applicant believes that the rejections were already overcome. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1-11, 13, 15-25, and 27

Claims 1-11, 13, 15-25, and 27 stand rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent 5,291,896 to Fonger et al. ("Fonger") in view of U.S. Publication 2003/0097082 to Purdy et al. ("Purdy"). The Examiner argues that Fonger teaches the claimed invention except for (a) the distally disposed pressure sensor embedded in a distal portion of the catheter, as recited in claims 1 and 18, and (b) the at least one wire having a proximal end mated to an external antenna, as recited in claim 18. The Examiner relies on Purdy to teach these features, arguing that it would have been obvious to modify the device of Fonger in view of Purdy to arrive at the claimed invention. As set forth on pg. 4 of the October 4, 2007 Office Action, the Examiner appears to be relying on Section III(A) of the "Examination Guidelines for Determining Obviousness Under 35 U.S.C 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*" (hereinafter "the Guidelines"). To reject a claim based on the rationale under Section III(A) of the Guidelines, the Examiner must articulate, among other requirements,:

> a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that ***in combination, each element merely would have performed the same function as it did separately***. (Emphasis added).

A person having ordinary skill in the art would have no motivation to modify the device of Fonger to include a distally disposed pressure sensor embedded or disposed in a wall in a distal portion of the catheter. Applicant refers the panel to arguments set forth on pgs. 7-8 of the Amendment and Response filed on January 2, 2008. Combining Fonger with Purdy does not yield a combination where each element performs the same function as it did separately. In fact, the pressure sensor of Fonger would function markedly different in combination with Purdy than it does separately. The basic principle of Fonger is to provide a sensor that is *released* from a catheter to enable the sensor to be *implanted* in an *exterior surface* of a vessel to externally detect the pressure within the vessel through the vessel wall. Modifying Fonger in view of Purdy to embed or dispose the sensor in a distal portion of the catheter would change the function performed by the sensor.

Specifically, such a modification would prevent Fonger's pressure sensor from being *released* from the catheter to allow the sensor to be *implanted* in an *exterior surface* of a vessel. Rather, the combination would yield a pressure sensor that is fixed on a distal portion of a catheter and unable to implant in any surface. Moreover, the Fonger device is designed to externally measure the pressure in the heart through the vessel wall. Modifying Fonger to include an embedded sensor would frustrate this purpose, as the modified catheter would have to be inserted into a vessel defeating the entire purpose of Fonger. Thus, embedding or disposing the sensor of Fonger in the catheter, as required by independent claims 1 and 18, is not merely a simple substitution of known elements as the combination does *not* yield a device that performs the same function as it did separately. Rather, the combined device is much more invasive and functions markedly different than the device contemplated by Fonger.

In response to Applicant's above argument, the Examiner asserts that:

> ...the function of the sensors as taught by both Fonger and Purdy is to measure pressure and to substitute one distally disposed pressure sensor configuration for another ***achieves the predictable results of measuring a pressure of a fluid surrounding the distal portion of the catheter*** via distally disposed pressure sensor configuration in a pressure measurement catheter system, thus to substitute the pressure sensor configuration as taught by Fonger by ***embedding the pressure sensor configuration as taught by Purdy in a distal portion of the catheter as taught by Fonger would not change the function performed by the sensor because both sensor configurations function to measure pressure.***

(Office Action dated March 13, 2008, pg. 7; Emphasis added). The Examiner's reasoning is flawed for a number of reasons. As an initial matter, the Examiner incorrectly states that the pressure sensor disclosed by Fonger measures the *pressure of a fluid surrounding the distal portion of the catheter.* Contrary to the Examiner's assertion, Fonger's pressure sensor *externally* measures the pressure *within* a vessel *through* the vessel wall – not the pressure of fluid surrounding the distal portion of the catheter as asserted by the Examiner. Thus, the modification proposed by the Examiner does indeed change the function performed by the Fonger sensor because the modified sensor could no longer *externally* measure the *internal* vessel pressure *through* the vessel wall, as the modified sensor would have to be inserted into the vessel to measure the pressure therein. Moreover, the Examiner also

incorrectly asserts that because the modified Fonger sensor still measures pressure it thus performs the same function as it did prior to the combination and therefore yields predictable results. The Examiner has oversimplified the function of the Fonger sensor by asserting that it is merely a pressure sensor. As explained above, the Fonger sensor functions to *externally* measure the pressure within a vessel *through* the wall of the vessel. The modified Fonger sensor does not perform the same function as the original, as it is no longer capable of *externally* measuring the internal vessel pressure since it can no longer be implanted in the vessel wall. Thus, the modified sensor is not a predicitable result.

Accordingly, independent claims 1 and 18, as well as claims 2-17, 19-25, and 27 which depend directly or indirectly therefrom, distinguish over Fonger and Purdy, taken alone or combined, and represent allowable subject matter.

Applicant further notes that independent claim 18 additionally requires an antenna coupled a proximal end of a wire extending through the catheter. One having ordinary skill in the art would not be motivated to modify the device of Fonger to include an antenna as taught by Purdy. Applicant refers the panel to arguments set forth on pg. 8 of the Amendment and Response filed on January 2, 2008. In response to Applicant's argument that there is no motivation to modify the cardiac output probe of Fonger to include an antenna as taught by Purdy because such a modification would require a substantial reconstruction and redesign of the Fonger probe, the Examiner asserts that:

> ...one of ordinary skill in the art at the time of the invention would be knowledgeable of the substitution or replaceability of various configurations of data communication aiding in measuring pressure, each providing a means for the transmission of data in pressure measurement.

(Office Action dated March 13, 2008, pg. 8). The mere fact that the Fonger probe *may be modified* to replace the hardwired data communications with an antenna does not mean that a person skilled in the art would be motivated to make such a modification. As explained by Applicant in the second full paragraph on pg. 8 of the Amendment and Response filed on January 2, 2008, because the Fonger probe is specifically designed for in-hospital use when the patient is under the direct supervision of a physician, there is simply *no need* to modify Fonger to include an antenna for remote communication, as taught by Purdy. Moreover, such a modification is also not a simple

substitution, as the detector of Fonger is not configured to work with an antenna. The modification would require that the sensor be entirely reconstructed or replaced to allow for use with an antenna. Accordingly, claim 18, as well as claims 19-25 and 27 which depend therefrom, further distinguish over Fonger and Purdy, taken alone or combined, and represent allowable subject matter.

Conclusion

In view of the above remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested.

Respectfully submitted,

Date: June 11, 2008

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PENDING CLAIMS

1. (Previously Presented) An implantable fluid management device, comprising:

an elongate catheter having a proximal end, a distal end, and a first inner lumen extending therethrough;

a sensor embedded in a distal portion of the catheter such that the sensor is effective to measure a pressure of fluid surrounding the distal portion of the catheter;

at least one wire having a distal end coupled to the sensor and having a proximal end that is adapted to mate to an external component for powering and/or communicating with the sensor, the at least one wire extending along a length of the catheter such that the at least one wire is in fluid isolation from the inner lumen of the catheter, and the at least one wire being separable from a proximal portion of the catheter such that the length of the catheter is selectively adjustable.

2. (Original) The device of claim 1, wherein the at least one wire is disposed within a second lumen that is isolated from the first lumen.

3. (Original) The device of claim 2, further comprising a slit extending through an outer wall of the catheter into the second lumen, the slit extending along at least a portion of a length of the catheter from the proximal end thereof such that a portion of the at least one wire can be at least partially removed from the catheter through the slit to allow the length of the catheter to selectively adjusted.

4. (Original) The device of claim 2, wherein the first lumen has a diameter that is greater than a diameter of the second lumen.

5. (Original) The device of claim 2, wherein the second lumen is formed within an invagination of the outer wall of the catheter extending within the first lumen.

6. (Original) The device of claim 1, further comprising a slit extending through an outer wall of the catheter along at least a portion of a length of the catheter from the proximal end thereof such that

a portion of the at least one wire can be at least partially removed from the catheter through the slit to allow the length of the catheter to selectively adjusted.

7. (Original) The device of claim 6, wherein the slit extends along a distance less than the length of the catheter.

8. (Original) The device of claim 6, wherein the slit extends along less than about one half of the length of the catheter.

9. (Original) The device of claim 6, wherein the slit is substantially fluid impermeable in a closed position.

10. (Original) The device of claim 6, wherein the catheter is made from a material that is self-sealing.

11. (Original) The device of claim 6, wherein the at least one wire is disposed within a second lumen that is isolated from the first lumen and the slit extends into the second lumen.

12. (Original) The device of claim 1, wherein the at least one wire is disposed within a secondary catheter that is coupled to the catheter and that can be peeled apart from the catheter to allow the length of the catheter to be selectively adjustable, independent of the length of the secondary catheter.

13. (Original) The device of claim 1, wherein the catheter is formed from a flexible, biocompatible polymer.

14. (Original) The device of claim 1, wherein the catheter is formed from a polymer selected from the group consisting of silicones, silicone-like materials, and polyurethanes.

15. (Original) The device of claim 1, wherein the sensor is disposed with a wall of the catheter such that the sensor is adapted to sense conditions adjacent to the catheter.

16. (Original) The device of claim 1, wherein the sensor is a pressure sensor.

17. (Original) The device of claim 1, wherein the sensor has a diameter that is equal to or less than about 3 mm.

18. (Previously Presented) An implantable fluid management device, comprising:

an elongate catheter having a proximal end, a distal end, and first and second inner lumens extending therethrough and isolated from one another;

a sensor disposed within a wall of a distal portion of the catheter such that the sensor is adapted to sense conditions present around the catheter;

at least one wire extending through the second lumen in the catheter and having a distal end coupled to the sensor and a proximal end mated to an external antenna; and

a slit extending through an outer wall of the catheter into the second lumen along at least a portion of a length thereof such that a portion of the at least one wire can be at least partially removed from the catheter through the slit to allow the length of the catheter to be selectively adjustable.

19. (Original) The device of claim 18, wherein the first lumen has a diameter that is greater than a diameter of the second lumen.

20. (Original) The device of claim 18, wherein the second lumen is formed within an invagination of the outer wall of the catheter extending within the first lumen.

21. (Original) The device of claim 18, wherein the slit extends along a distance less than the length of the catheter.

22. (Original) The device of claim 18, wherein the slit extends along less than about one half of the length of the catheter.

23. (Original) The device of claim 18, wherein the slit is substantially fluid impermeable in a closed position.

24. (Original) The device of claim 18, wherein the catheter is made from a material that is self-sealing.

25. (Original) The device of claim 18, wherein the catheter is formed from a flexible, biocompatible polymer.

26. (Canceled).

27. (Original) The device of claim 18, wherein the sensor is a pressure sensor.

28-35. (Canceled).

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